JUSTISI

Vol. 11, Issue. 1, January 2025
e-ISSN: 2686-0821, p-ISSN: 1979-7532

https://ejournal.um-sorong.ac.id/index.php/js/article/view/3644

Article History
Received: 12 Aug 2024
Reviewed: 06 Oct 2024
Accepted: 16 Nov 2024
Published: 20 Nov 2024

Legal Protection for Medical Laboratories Concerning Risk-Based Business Licensing Standards and the Fulfillment of Clinical Pathology Specialist

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Abstract: Medical laboratories play a crucial role in the healthcare system but often face regulatory challenges, particularly in the context of licensing. The amendment to the Ministry of Health Regulation on the Standards of Business Activities and Risk-Based Licensing in the Health Sector, which requires Clinical Pathology Specialists (DSPK) as the responsible physician, replacing general practitioners, has created difficulties for medical laboratory operators. The main issue is the uneven distribution of DSPK across Indonesia, which impacts the operation of medical laboratories. This research aims to analyze the legal protection of medical laboratories concerning the fulfillment of risk-based business licensing standards, particularly regarding the requirement for DSPK. The research employs a normative juridical method by examining relevant laws, government regulations, and judicial decisions. The results indicate that in the formulation of regulation, the legislative rationale must consider philosophical, sociological, and juridical aspects. However, the sociological aspects is not fully addressed due to the uneven distribution of DSPK, rendering the regulation ineffective at the national level. This issue hampers public access to quality laboratory services. Therefore, legal protection is needed to ensure that national health standards are achieved without creating disparities in access to healthcare services across different regions.

Keywords: Health Sector; Licensing; Medical Laboratory; Minister of Health Regulation; Protection.

Abstrak: *Laboratorium medis memiliki peran vital dalam sistem kesehatan, namun seringkali menghadapi tantangan regulasi, khususnya terkait perizinan. Perubahan Peraturan Menteri Kesehatan tentang Standar Kegiatan Usaha dan produk Perizinan Berusaha Berbasis Risiko Sektor Kesehatan, mensyaratkan Dokter Patologi Klinik (DSPK) sebagai dokter penanggung jawab menggantikan dokter umum, sehingga menimbulkan kesulitan bagi pelaku usaha laboratorium medis. Masalah utamanya adalah ketidakmerataan distribusi DSPK di seluruh wilayah Indonesia, yang berdampak pada operasional laboratorium medis. Riset ini bertujuan untuk menganalisis perlindungan hukum terhadap laboratorium medis terkait pemenuhan standar perizinan usaha berbasis risiko, khususnya pemenuhan DSPK. Metode penelitian yang digunakan adalah yuridis normatif dengan mengkaji undang-undang, peraturan pemerintah, dan keputusan yudisial yang relevan. Hasil penelitian menunjukkan bahwa dalam pembuatan peraturan, rasio legis harus memperhatikan aspek filosofis, sosiologis, dan yuridis. Namun, unsur sosiologis tidak sepenuhnya terpenuhi karena kesenjangan distribusi DSPK*

menyebabkan penerapan Permenkes tidak efektif secara nasional. Masalah ini menghambat akses masyarakat terhadap pelayanan laboratorium yang berkualitas. Oleh karena itu, perlu perlindungan hukum yang memastikan tercapainya standar kesehatan nasional tanpa menimbulkan kesenjangan akses layanan kesehatan di berbagai daerah.
Kata Kunci: *Laboratorium medis; Perizinan; Perlindungan; Permenkes; Sektor kesehatan.*

INTRODUCTION

Health insurance is a key instrument related to the quality of a nation. Therefore, health is a fundamental human right, and public health is directly proportional to the quality of state development. In other words, developing and improving health services is a crucial investment in the governance and progress of a nation. The mandate of the Preamble to the 1945 Constitution (UUD 1945) and the fifth principle of Pancasila emphasize that social justice is the right of all people. Additionally, Article 28 H Paragraph (1) of the 1945 Constitution states, "Every person has the right to live in physical and spiritual well-being, to have a place to live, to have a good and healthy environment, and to receive health services." This series of mandates explicitly holds the government responsible for organizing comprehensive health services and ensuring that people live in a healthy manner. The task of health development includes providing the best services in the establishment of hospitals, health centers, pharmacies, laboratories, rehabilitation facilities, and more.[1]

In recent decades, Indonesia's health industry has undergone significant development, driven by the growing demand for quality and affordable healthcare services. This growth not only necessitates improvements in medical services but also requires legal certainty to protect various aspects of health facility operations. As an integral part of the healthcare system, medical laboratories play a crucial role in diagnosis, treatment, and patient monitoring. Therefore, to meet the licensing standards for medical laboratories, the presence of Clinical Pathology Specialists is considered essential, as they play a central role in interpreting laboratory test results, which serve as the foundation for patient diagnosis and treatment.

The Regulation of the Minister of Health (Permenkes) Number 14 of 2021 concerning Business Activity and Product Standards in the Implementation of Risk-Based Business Licensing in the Health Sector states that medical laboratories are a part of health laboratories, which conduct clinical specimen tests to obtain information about patient health related to diagnosis, management, disease monitoring, prognosis, and disease prevention.[2] However, in practice, medical laboratory operations in Indonesia often face various challenges, particularly in meeting risk-based business licensing standards. One significant challenge is the uneven distribution of Clinical Pathology Specialists in certain regions, which leads to disparities in fulfilling these standards and can negatively impact the quality of medical laboratory services in underserved areas.

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[1] Kementerian Kesehatan Republik Indonesia, *Profil Kesehatan Indonesia 2022*, n.d.

[2] 'Persebaran Dokter Di Indonesia Belum Merata, 70 Persen Masih Berpusat Di Pulau Jawa – Universitas Muhammadiyah Yogyakarta', accessed 7 August 2024, https://www.umy.ac.id/persebaran-dokter-di-indonesia-belum-merata-70-persen-masih-berpusat-di-pulau-jawa.

Ernawati (2021) highlights the dynamics of business licensing and clinic operations in Indonesia as regulated by the Job Creation Law, which not only alters the regulatory landscape but also simplifies previously complex licensing procedures.[3] Meanwhile, Johan (2020) emphasizes business licensing reform, noting that regents and mayors are granted authority to manage low and medium-risk licenses, while governors oversee high-risk businesses to foster an efficient business climate in Indonesia.[4] Both studies provide insights into the dynamics of licensing and regulatory reform in Indonesia, yet they leave gaps, particularly concerning the fulfillment of a key requirement for high-risk licensing: the presence of a Clinical Pathology Specialist.

The presence of a Clinical Pathology Specialist is essential for ensuring the quality and accuracy of medical services, and it serves as a key indicator for meeting the operational standards set by the government. This study aims to explore the legal basis for the amendment of the Minister of Health Regulation Number 14 of 2021 concerning Business Activity Standards and Risk-Based Business Licensing Products in the Health Sector, particularly regarding the shift in responsibility for clinical laboratories from General Practitioners to Clinical Pathology Specialists as a licensing requirement. Additionally, the study examines the legal protection for medical laboratories as Limited Liability Company (PT) legal entities within the framework of risk-based business licensing in the health sector.

METHOD

The method used in this research is normative juridical, a legal research approach that involves examining literature related to the alignment of local regulations with human rights. Qualitative analysis is employed descriptively within normative jurisprudence to analyze policies aimed at improving the performance of the legal system in Indonesia, followed by an in-depth study based on normative provisions. Primary sources in normative jurisprudence include legislation pertinent to the research topic and formulated problems. Additionally, normative jurisprudence examines written law from various aspects, including theory, history, philosophy, comparison, structure and composition, scope and material, consistency, general explanation, article-by-article analysis, formality, and binding force, as well as the language used in the law. However, it does not address aspects of application or implementation.[5]

DISCUSSION

Ratio Legis for the Establishment of Minister of Health Regulations on Business Activity Standards and Risk-Based Business Licensing Products in the Health Sector

In the era of globalization, the health sector faces various challenges that necessitate appropriate and adaptive regulations to align with contemporary dynamics and community

[3] Titik Ernawati, 'Aspek Hukum Perizinan Berusaha Dan Operasional Pada Klinik Utama Dengan Diberlakukannya Undang-Undang Cipta Kerja' (Tesis, Surabaya, Universitas Hang Tuah, 2021).
[4] Johan, 'Perizinan Berusaha Di Daerah Dalam Persepektif Undang-Undang Nomor 11 Tahun 2020 Tentang Cipta Kerja' (Kalimantan Utara, Fakultas Hukum Universitas Borneo Tarakan, 2022).
[5] Peter Mahmud Marzuki, 'Penelitian Hukum', 2013, http://library.stik-ptik.ac.id/detail?id=49216&lokasi=lokal.

needs. The Minister of Health Regulation concerning Business Activity Standards and Risk-Based Business Licensing Products is a significant effort in regulating business activities in the health sector. Understanding the ratio legis, or the legal basis and purpose behind the formation of a regulation, is crucial in this context. Ratio legis refers to the legal reasoning or rationale behind the creation of a regulation or law. Conceptually, the ratio legis serves as the foundation that explains both the reasons for enacting a regulation and the objectives it aims to achieve. In this case, the ratio legis reflects the purpose, motivation, and needs driving the formation of the regulation.

Manan, as cited in Asshiddiqie, explained that to produce robust and high-quality laws, they must be based on philosophical, sociological and a juridical. Through these three foundations, state legal products, including laws, are developed systematically, transparently, and participatively by the House of Representatives, the President, and the Regional Representatives Council. This approach aims to ensure that community life, government operations, and the economy function smoothly and fairly.[6]

As mentioned earlier, in the context of legislative development, ratio legis serves as the fundamental principle underlying a law, akin to the nature of the law itself. A clear and robust ratio legis is expected to ensure that the establishment of the Minister of Health Regulation effectively meets the objectives of health law and policy. This, in turn, should provide legal certainty and enhance the accessibility of health services for the entire community. A well-defined ratio legis guarantees that the regulation is based on logical and thorough reasoning, allowing it to address the needs and rights of the community comprehensively within the health sector. Consequently, the Minister of Health Regulation functions not only as a regulatory tool but also as a means to achieve justice and welfare in the health sector. Therefore, the formation of laws and regulations must adhere to the principles of legislative science (*gesetzgebungslehre*).

The philosophical foundation in law formation signifies that a law gains its authority when it aligns with the ideals of law (rechtsidee) as the highest positive values,[7] encompassing beneficial goals, moral and ethical values, and paradigms.[8] This foundation is articulated in the primary considerations of laws, provincial regulations, or district/city regulations. The philosophical foundation provides the underlying ideas that guide the creation of regulations. It is a critical consideration in the regulatory formation process, which progresses from philosophical, to sociological, to juridical aspects. The philosophical elements include considerations or reasons that demonstrate how the regulations reflect the worldview, awareness, and legal ideals of the Indonesian nation, derived from Pancasila and the Preamble

[6] Virginia Viona Verariza and Rehnalemken Ginting, 'Ratio Legis Pengaturan Rehabilitasi Dalam Tindak Pidana Narkotika (Studi Putusan Nomor: 114/ Pid.Sus/ 2020/ PN.Lbo)', *Recidive : Jurnal Hukum Pidana Dan Penanggulangan Kejahatan,* 11 (1), 2022. 29–35, https://doi.org/10.20961/recidive.v11i1.67426.

[7] Jimly Asshiddiqie, *Perihal Undang-Undang*, 5th ed. (Jakarta: Rajawali Perss, 2020).

[8] JJ. H Bruggink, *Refleksi Tentang Hukum : Pengertian-Pengertian Dasar Dalam Teori Hukum*, Terj. Arief Sidharta. Bandung: Citra Aditya Bhakti, 2015.

to the 1945 Constitution of the Republic of Indonesia.[9]

Legal content should capture the aspirations of a growing and evolving society, addressing not only current needs but also serving as a reference for anticipating future social, economic, cultural, and political developments. This aligns with Roscoe Pound's concept,[10] which posits that to strengthen societal civilization, social control is necessary to regulate behavior that deviates from social norms. Pound also emphasized the role of law in maintaining discipline through his theory of "Law as a Tool of Social Engineering," which views law as a means to renew or reshape society.[11]

As a tool of justice for addressing social problems, the law must balance individual and societal interests, requiring it to be adaptive and flexible. In this context, the sociological foundation reflects the state of society or the reality of social interactions. This foundation demonstrates that regulations aim to meet societal needs across various aspects, including economic, social, cultural, and political.[12] The sociological foundation is grounded in empirical facts that describe societal problems and needs, ensuring that the law functions effectively and remains relevant to the current context.[13]

Thus, the law serves not only as a regulatory tool but also as a reflection of social dynamics. By incorporating sociological aspects, the formation of laws and regulations can be more responsive to societal changes and challenges. This foundation ensures that laws not only regulate but also provide tangible benefits to the community, addressing the evolving needs and aspirations of society. Consequently, the law becomes an instrument that not only regulates but also serves and protects society, aligning with the principles of genuine social justice.

In addition to the philosophical foundation, which serves as a reference in regulation-making by containing core ideas, and the sociological foundation, which addresses society's needs across various aspects of life, the juridical foundation is essential for considerations or reasons that justify the creation of a regulation. This foundation ensures that regulations are designed to address legal issues or fill legal gaps by considering existing rules that may need to be amended or repealed to ensure legal certainty and justice for the community.[14] The juridical foundation is a crucial aspect of law and regulation formation because it addresses the legal issues related to the substance or material being regulated. It emphasizes the necessity for new regulations to resolve various legal problems, such as conflicts or overlaps between existing regulations, or regulations that are outdated and no longer align with the current context.

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[9] Ibid.

[10] Roscoe Pound adalah ahli hukum pertama menganalisis yurisprudensi serta metodologi ilmu-ilmu sosial.

[11] Nazaruddin Lathif, 'Teori Hukum Sebagai Sarana / Alat Untuk Memperbaharui Atau Merekayasa Masyarakat', *Pakuan Law Review,* 3(1), 2017.

[12] Otti Ilham Khair, 'Analisis Landasan Filosofis, Sosiologis Dan Yuridis Pada Pembentukan Undang-Undang Ibu Kota Negara', *ACADEMIA : Jurnal Inovasi Riset Akademik,* 2(1), 2022.

[13] Zainal Arifin Hoesein, 'Pembentukan Hukum Dalam Perspektif Pembaruan Hukum', *Jurnal Rechts Vinding: Media Pembinaan Hukum Nasional*, 1(3), 2012. 307–27, https://doi.org/10.33331/rechtsvinding.v1i3.87.

[14] Rosjidi Ranggawidjaja, *Pengantar Ilmu Perundang-Undangan Indonesia*. Bandung: Mandar Maju, 1998.

In the context of the Ministry of Health, a juridical basis is crucial, as the ministry's tasks often stem from Presidential directives issued in the form of Presidential Regulations. These regulations are then followed up with more specific and technical Ministerial Regulations. This process ensures that health policies are not only legally sound and consistent with existing laws but also capable of addressing health issues within the community. A strong juridical foundation allows the Ministry of Health to implement policies effectively, as they are grounded in law and judicial principles. Moreover, it enables the Ministry to develop policies that are responsive to changes in social conditions and meet the needs of the community. Therefore, regulations are crafted not only to satisfy legal requirements but also to be relevant and beneficial in practice.

The philosophical foundation encompasses the basic principles and legal ideals that guide the creation of regulations, reflecting the worldview, awareness, and values upheld by society. The sociological foundation addresses the state of society or the existing reality, while the juridical foundation pertains to the legal and technical aspects that ensure the regulation is lawful, consistent, and properly enforceable, aligning with existing legal frameworks. Therefore, a law-making process that considers these three foundations will produce regulations that are not only legally valid but also rooted in societal values and needs, ultimately providing tangible benefits for social life.[15] The judicial basis is a crucial aspect in the formation of statutory regulations, because it concerns legal issues related to the substance or material being regulated. The judicial basis emphasizes the need for new regulations to overcome various legal problems, such as regulations that are not harmonious/overlapping, or are no longer appropriate to the current context (outdated).

The position of Ministerial Regulations in Indonesia's legal hierarchy is addressed in Article 8 of Law Number 12 of 2011, as amended by Law Number 15 of 2019. However, the law does not explicitly specify the exact position of Ministerial Regulations within the hierarchical system of laws and regulations. Ministerial Regulations, including those issued by the Minister of Health, are enacted by the minister based on their duties and authority in their respective fields to manage specific governmental affairs. The implementation of these duties by the Minister of Health is inherently linked to the highest legal frameworks. In fulfilling its responsibilities, the ministry operates under constitutional authority, carrying out control functions and maintaining checks and balances both within and across institutions and sectors. This approach is designed to minimize the potential for abuse of power.[16]

Health Ministerial Regulations play a crucial role in ensuring that health policies are aligned with the existing legal framework and effectively address emerging health issues. Although the position of Ministerial Regulations is not explicitly outlined in the legal hierarchy, these regulations remain significant in governance and public services, particularly within the health sector.

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[15] Ranggawidjaja.

[16] Dewi Nawang Wulan et al., 'Ratio Legis Kewenangan Diskresioner Kementerian Kesehatan Terkait Regulasi Komersialisasi Vaksin Gotong Royong Corona Virus Disease- 2019 (COVID-19)', *Perspektif Hukum*, 20 April 2022, 53–79, https://doi.org/10.30649/ph.v22i1.102.

In government administration, Ministerial Regulations are vital because not all regulations created by the government can be effectively implemented without them. Normatively, Ministerial Regulations—especially those issued by the Ministry of Health—are recognized and have binding legal force as long as they are mandated by higher laws or established based on the minister's authority. These regulations are essential for translating broader government policies into more specific and applicable rules, thereby facilitating the implementation of higher-level regulations.[17]

The ratio legis behind the establishment of Minister of Health Regulation Number 14 of 2021, which governs standards for business activities and risk-based business licensing in the health sector, is grounded in several key perspectives. Philosophically, this regulation reflects the core values of Pancasila. Sociologically, it aims to address the evolving needs and challenges within the health sector, ensuring the quality and accountability of services in medical laboratories. However, in practice, the availability of Clinical Pathology Specialists—who are required as the responsible doctors in medical laboratories—remains a significant challenge due to their uneven distribution across Indonesia. The limitation of a Clinical Pathology Specialist's Practice License to just three practice sites further exacerbates the shortage, failing to meet the demand in many medical laboratories.

Data from provincial and municipal health offices highlight a disparity between the number of Clinical Pathology Specialists and the number of medical laboratories, particularly in smaller cities and districts. As a result, the implementation of Minister of Health Number 14 of 2021 is difficult to achieve in these areas, unlike in larger cities where the distribution of Clinical Pathology Specialists is more balanced. Nonetheless, the shift from general practitioners to Clinical Pathology Specialists as a standard has positively impacted laboratory services, as it ensures higher quality and more accurate diagnostics.

Legally, the establishment of this Ministerial Regulation is an effort to update outdated regulations and ensure legal certainty for business actors through standardized guidelines, aligned with the risk level of their business activities. The presence of Clinical Pathology Specialists, adhering to clinical pathology competency standards, guarantees that the results of medical laboratory examinations overseen by a Clinical Pathology Specialist are valid health documents. Despite the limited number of Clinical Pathology Specialists and the restriction of practice licenses to only three locations, it is essential to implement regional regulations to address the need for Clinical Pathology Specialist Practice Licenses, especially for doctors in charge of medical laboratories at the primary and intermediate levels.

The implementation of risk-based business licensing in the health sector, specifically in medical laboratories for fulfilling the need for Clinical Pathology Specialists, as stipulated by the Regulation of the Minister of Health of the Republic of Indonesia Number 14 of 2021 on Business Activity Standards and Risk-Based Business Licensing Products in the Health Sector, faces significant challenges. A major obstacle is the uneven distribution of Clinical Pathology

[17] Ni'matul Huda, 'Kedudukan Dan Materi Muatan Peraturan Menteri Dalam Perspektif Sistem Presidensial', *Jurnal Hukum IUS QUIA IUSTUM*, 28(3), 2021. 550–71, https://doi.org/10.20885/iustum.vol28.iss3.art5.

Specialists across all regions of Indonesia, making it difficult to meet the required standards. Furthermore, determining the fulfillment of medical rights or services for Clinical Pathology Specialists in medical laboratories is also complex. According to professional and certification standards, medical services for Clinical Pathology Specialists in independent clinical laboratories and laboratories at Level 1 Health Service Providers consist of two types: flat-rate medical services and action-based medical services. Flat-rate medical services are fixed rewards for the expertise of Clinical Pathology Specialists, while action-based medical services are provided based on the specific examinations conducted by Clinical Pathology Specialists, in accordance with their professional standards and certification.

Full Timer

Full-time Clinical Pathologists with one license to practice and one registration certificate are on duty every working day. They receive both flat-rate medical fees and action-based service fees. The flat-rate medical fee for Clinical Pathology Specialists in Main or Intermediate Clinical Laboratories and Main PPK 1 Laboratories is at least IDR 40 million per month, while for Primary Clinical Laboratories or Primary PPK 1 Laboratories, it is at least IDR 30 million per month. Additionally, they receive action-based fees, including 50% of the peripheral blood smear examination rate, 70% of the bone marrow smear examination rate, 70% of the myelogram examination rate, and 30% of other examination rates. For Medical Check-Up (MCU) Lab result expertise, Clinical Pathology Specialists receive a minimum fee of IDR 10,000 per patient, and for consultation and presentation of MCU results, they receive a minimum of IDR 1 million per presentation.

Part Timer

Clinical Pathology Specialists who work part-time at Independent Clinical Laboratories or PPK 1 Laboratories, attending 1-3 times per week, also receive flat-rate medical fees plus action-based service fees. The flat-rate medical fee for Clinical Pathology Specialists at Main or Intermediate Clinical Laboratories and Main PPK 1 Clinical Laboratories is at least IDR 20 million per month, while at Primary Clinical Laboratories or Primary PPK 1 Clinical Laboratories, it is at least IDR 10 million per month. Additionally, they receive action-based fees, including 50% of the peripheral blood smear examination rate, 70% of the bone marrow smear examination rate, 70% of the myelogram examination rate, and 30% of other examination rates. For Medical Check-Up (MCU) Lab result expertise, Clinical Pathology Specialists receive a minimum fee of IDR 10,000 per patient, and for consultation and presentation of MCU results, they receive a minimum of IDR 1 million per presentation.

The determination of medical service fees according to the above standards places a heavy burden on Primary Medical Laboratories in regional areas, where laboratory service rates tend to be lower than those in big cities. Negotiations over the fulfillment of medical service fees often fail to reach an agreement between business owners and Clinical Pathology Specialists. Article 5 of the Law of the Republic of Indonesia Number 12 of 2011 stipulates that every piece of legislation must be based on the principles of usefulness and usability, meaning that the regulation must be truly necessary and beneficial in governing the life of society, the

nation, and the state.

The regulation of additional Practice Licenses for Clinical Pathology Specialists in areas with uneven distribution is a crucial step in meeting the need for these specialists to oversee medical laboratories. This regulation is based on data regarding the human resources of Clinical Pathology Specialists at the district, city, and provincial levels. Ensuring equitable access to essential health services is a governmental responsibility, aimed at improving the overall health and quality of life of the community. The establishment of implementing regulations at the regional level, issued by relevant local leaders and officials, provides clarity and legal certainty for the procedures involved in granting recommendations, which are necessary for the effective and accountable issuance of Practice Licenses. Mapping the number of medical laboratories and Clinical Pathology Specialists should be a key focus in addressing issues related to meeting Medical Laboratory licensing standards.

For example, Situbondo Regent Regulation Number 5 of 2024 establishes guidelines for providing recommendations for the issuance of Practice Licenses. This regulation governs the placement of practice assignments for specialist doctors, recommending two practice locations: Regional General Hospitals and other health service facilities. This regent regulation further stipulates that Specialist Doctors be assigned to two practice sites: one in a Regional General Hospital and one in another health service facility. To date, there is no government regulation addressing the issuance of additional practice licenses for Clinical Pathology Specialists by provincial and district/city governments in areas where the distribution of these specialists is uneven.

The Ratio Legis of Minister of Health Regulation Number 14 of 2021 does not fully satisfy the sociological elements or the principles of validity and usefulness for nationwide application. While the determination of these two types of medical services aims to recognize and appreciate the competence and contribution of Clinical Pathology Specialists in their duties, the implementation of this standard remains challenging due to the uneven distribution of human resources and the need to fulfill medical rights in accordance with existing regulations.

Legal Protection for Medical Laboratories as Limited Liability Entities in Relation to Risk-Based Business Licensing in the Health Sector

Business licensing is a form of authorization granted by the competent authority as a legal requirement before business actors can start or conduct their business activities. According to Article 6 of Government Regulation of the Republic of Indonesia Number 5 of 2021 concerning the Implementation of Risk-Based Business Licensing, business actors are required to obtain a risk-based business license before commencing or conducting business activities. Additionally, business actors must fulfill the basic requirements for the business activities they intend to carry out. Risk-based business licensing is a new framework introduced as part of Law Number 6 of 2023 concerning Job Creation.[18]

[18] Erni Erni and Febri Jaya, 'Efektifitas Perizinan Berusaha Berbasis Risiko Dalam Rangka Kemudahan Berusaha', *Wajah Hukum,* 6(2), 2022. 248–57, https://doi.org/10.33087/wjh.v6i2.927.

The risk-based licensing approach is an application of the risk-based approach that emerged in response to the 'Regulatory State' concept developed in the 1980s. In this concept, the state plays a dominant role in monitoring, creating, and enforcing rules through bureaucratic organs managed by the state. The Regulatory State is characterized by a clear separation between regulatory functions and public service functions, as well as a distinction between regulatory functions and policy-making. Institutions performing regulatory functions are not involved in politics, while rule- and policy-makers operate at different stages in the decision-making process. This approach allows the state to focus on producing regulations designed to organize people's lives in a structured and directed manner.[19]

The OSS-RBA system, implemented on August 9, 2021, represents a digitalization of public service mechanisms, particularly in business licensing. This electronic business licensing system offers easy access to the public, allowing permit processing to occur anywhere and anytime, without the need to visit the One Stop Integrated Service. The goal of digitalization is to simplify business processes and accelerate investment. Additionally, the OSS-RBA system is integrated with various other systems, such as AHU Online, DJP Online, and LKPM, resulting in more efficient data synchronization. Juridically, to ensure the validity, accuracy, and authenticity of operations, laboratories are required to possess various important documents, including legal entity status, proof of identity, Company Register, Taxpayer Identification Number, and Company License. These documents not only fulfill general requirements but also serve as the basis for the legitimacy of the laboratory's operations

In terms of cost, risk-based business licensing is essentially free of charge. However, if any costs are incurred, all payments are made online through the OSS-RBA system in accordance with Non-Tax State Revenue provisions. Generally, these fees are associated with processing basic requirements, such as the Conformity of Space Utilization Activities or retributions incurred during the processing of Building Construction Approval and the Certificate of Functioning Fitness. Additionally, there may be extra costs if a third party is involved, such as consultant fees. These fees are necessary for providing expertise in meeting the basic requirements of the approval process.[20]

Legal entities are legal subjects that operate alongside human legal subjects. In legal terminology, legal entities in Dutch are referred to as rechtspersoon, while humans as legal subjects are called natuurlijke persoon. In English, legal entities are known as legal persons, and humans as legal subjects are called natural persons.[21] A legal entity is an organization or body regulated by law that has rights and obligations similar to those of individuals. This is because legal entities possess distinct purposes and assets separate from those of the

[19] Merissa Bhernaded Lie, 'Sistem Perizinan Berbasis Risiko: Sebuah Perbandingan Antara Negara Australia Dan Negara Indonesia', *JAPHTN-HAN,* 1(2), 2022. 169–85, https://doi.org/10.55292/japhtnhan.v1i2.30.

[20] Honny David Kansil, Een N Walewangko, and Vecky A.J Masinambow, 'Analisis Perizinan Berusaha Berbasis Risiko Untuk Meningkatkan Ease Of Doing Business Pada Kota Manado', *Jurnal Pembangunan Ekonomi Dan Keuangan Daerah,* 25(1), 2024, 27.

[21] A. A. Gede D. H. Santosa, 'Perbedaan Badan Hukum Publik Dan Badan Hukum Privat', *Jurnal Komunikasi Hukum (JKH),* 5(2), 2019. 152–66, https://doi.org/10.23887/jkh.v5i2.18468.

individuals who control them.[22] A Limited Liability Company (LLC) is an entity with legal person status, meaning that a PT (Perseroan Terbatas) functions as an independent legal subjec.[23]

The requirement for legal entity status in medical laboratory licensing is outlined in the Decree of the Minister of Health Number 04/MENKES/SK/I/2002 concerning Private Health Laboratories. Article 5 states that 'Private Health Laboratories can be organized by individuals or legal entities.' In this context, a Limited Liability Company is one type of legal entity with limited liability on shares. Medical laboratories, as part of health facilities, are equipped with various biomedical instruments, equipment, materials, and reagents (chemicals) to conduct laboratory examinations using biological specimens such as blood, serum, plasma, urine, feces, and others. In summary, a clinical or medical laboratory is a facility where various tests are performed on biological specimens to obtain information about a patient's health.[24]

Clinical pathology specialists are expert doctors who play a crucial role in medical laboratories. They are recognized for meeting the standards of the Clinical Pathology profession and are equipped to perform activities in accordance with the competencies acquired through the Clinical Pathology Specialist Education Program. Their role encompasses medical, technical, and managerial aspects. Medically, they provide advice on the appropriate types of laboratory examinations based on clinical objectives, such as early detection, diagnosis, therapy monitoring, and prognosis determination, as well as interpreting examination results. This strategic position increases the responsibility of Clinical Pathology Specialists, as their duties extend beyond professional specialization to include clinical and managerial aspects within the laboratory. Therefore, it is essential to have professional standards that uphold the quality and professionalism of Clinical Pathology Specialists.[25]

Recent changes in regulations regarding the type of medical laboratory and the qualifications of the doctor in charge are outlined in Regulation of the Minister of Health Number 14 of 2021, which replaces the previous rules set forth in Regulation of the Minister of Health Number 411 of 2010 concerning Clinical Laboratories. As a result, medical laboratories are required to meet these new standards. The following is a detailed explanation of these changes:

Tabel 1. Amendment from Minister of Health Regulation Number 411 of 2010 concerning Clinical Laboratories to Minister of Health Regulation Number 14 of 2021 concerning Medical Laboratory Standards

Description	Permenkes No 411	Permenkes No 14
Mention of	Clinical Laboratory	Medical Laboratory

[22] Nandang Alamsah Deliarnoor, *Sistem Hukum Indonesia*, 2nd ed. (Tangerang Selatan: Universitas Terbuka, 2019).
[23] Fakhrurrahman Nur Qomariah Mhd, 'Prosedur Pembentukan Undang-Undang Di Indonesia Sebagai Negara Hukum', *Siyasah: Jurnal Hukum Tata Negara,* 6(1), 2023, http://ejournal.an-nadwah.ac.id/index.php/Siyasah/article/view/540.
[24] Eko Suprayogi, Budi Hartono, and Teguh Nurwanto, 'Peningkatan Mutu Dan Kemampuan Pelayanan Laboratoriumoratorium Di RS Harapan Sehati', *Jurnal ARSI* , 7(1), 2020.
[25] Perhimpunan Dokter Spesialis Patologi Klinik dan Kedokteran Laboratorium Indonesia, *Standar Profesi Dan Sertifikasi Dokter Spesialis Patologi Klinik*, 2019.

Classification	Pratama, Madya, Utama	Pratama, Utama
Technical Person in Charge	Pratama: A doctor with a certificate of technical training and laboratory management of at least 3 months conducted by the professional organisation of the Association of Clinical Pathology Specialists in collaboration with the Ministry of Health.	Pratama: Clinical Pathology Specialists
	Madya : Clinical Pathology Specialists	-
	Utama: Clinical Pathology Specialists	Utama: Clinical Pathology Specialists

Since the enactment of the Ciptakerja Law, a new concept has emerged regarding individual Limited Liability Companies that meet the criteria for Micro and Small Enterprises. An individual Limited Liability Companies can be established by a single person (natuurlijke persoon), making them the sole shareholder. Despite being established by only one shareholder, the principle of separate legal personality still applies, providing legal protection to the individual Limited Liability Companies shareholder.

Article 153J of the Limited Liability Company Law states that shareholders are not personally liable for agreements made on behalf of the company and are not responsible for company losses exceeding the value of their shares. However, there are exceptions to this limitation of liability, especially if the company has not yet achieved legal entity status. For example, if a shareholder uses the company for personal gain in bad faith or engages in unlawful activities using the company's assets, such that the company's assets are insufficient to cover its debts, liability may extend beyond the value of the shares owned.

According to the Big Indonesian Dictionary, legal protection is defined as the act of safeguarding individual rights from harm caused by others and ensuring that people can enjoy the rights guaranteed by law.[26] Legal protection aims to shield human rights that are infringed upon by others, so that individuals can fully enjoy all the rights guaranteed by law. This ensures that the rights of individuals within society are recognized, respected, and upheld fairly and equitably in accordance with applicable legal provisions.

The right to legal protection applies not only in civil law but also in constitutional, administrative, and public law.[27] Generally, legal protection is divided into two types:[28]

1. Preventive Protection: This type of protection allows individuals to file objections before

[26] Yos Johan Utama, 'Hukum Administrasi Negara (Edisi 2)', 2022, https://pustaka.ut.ac.id/lib/adpu4332-hukum-administrasi-negara-edisi-2/.
[27] Hans Kelsen, *Teori Umum Tentang Hukum Dan Negara*, VIII. Bandung: Nusa Media, 2013.
[28] Deliarnoor, *Sistem Hukum Indonesia*.

a government decision becomes final, with the aim of preventing disputes.

2. Repressive Protection: This type aims to resolve legal disputes that have already occurred.

In the implementation of legislation, repressive legal protection is more dominant compared to preventive legal protection, as seen in the Regulation of the Minister of Health of the Republic of Indonesia Number 14 of 2021 concerning Business Activity Standards and Risk-Based Business Licensing Products in the Health Sector, particularly KBLI 86903. This repressive protection is realized through various articles that address the resolution of legal issues that may arise, whether from disputes involving the legal entity of a PT medical laboratory or from the public using health services. Consequently, the lack of preventive legal protection underscores the importance of resolving disputes through the courts if non-litigation options are not feasible.

Medical laboratories incorporated as Limited Liability Companies have the right to file a lawsuit (judicial review) with the Supreme Court if Regulation Number 14 of 2021 is deemed unenforceable throughout Indonesia. Article 24C Paragraph (1) of the 1945 Constitution states that the Supreme Court has the authority to review laws and regulations against higher laws.

If this regulation does not comply with applicable provisions or contradicts higher laws and regulations, the medical laboratory, as a legal entity, can exercise its right to request a judicial review. This is particularly important because the regulation does not account for the distribution of Clinical Pathology Specialist Doctors and Specialist Doctor Education Programs, which take up to six years.

CONCLUSION

The rationale for establishing Regulation Number 14 of 2021 on Medical Laboratories must be based on three main pillars: philosophical, sociological, and juridical foundations. The philosophical foundation ensures that the regulation reflects fundamental values and noble principles. The sociological foundation aims for the regulation to address societal needs and respond to existing social developments. The juridical foundation emphasizes the importance of standardized medical laboratory licensing standards to ensure legal certainty and accountability in laboratory service results, in line with the competence of clinical pathology specialists. While the regulation has addressed the philosophical and juridical aspects, the sociological elements have not been fully met. This is due to the uneven distribution of Clinical Pathology Specialists across Indonesia, making comprehensive implementation of the Ministry of Health Regulation challenging. To address this issue, it is necessary to establish an Implementing Regulation at the regional level that governs the issuance of Practice Licenses, particularly in specific areas. This can be achieved through Governor Regulations and/or Regent/Mayor Regulations, which should be tailored to the distribution map of medical laboratories and the number of Clinical Pathology Specialists, based on data from Provincial and Regency/City Health Offices. Additionally, legal protection for medical laboratories, particularly those operating as Limited Liability Companies, must be considered. Preventive legal protection should be provided to prevent potential disputes, and if disputes cannot be avoided, they should be resolved through non-litigation channels. However, if non-litigation

resolution is unsuccessful, the next step would be to seek a judicial review through the Supreme Court. This is crucial to ensure that medical laboratories can operate in accordance with applicable legal provisions and continue to provide quality and accountable services.

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